

**Remarks**

Claims 1 and 8-12 are pending. Claims 1, 9, and 12 have been amended. Support for the claim amendment can be found on page 3, lines 21-22, of the specification. Importantly, no new matter has been added to the claims. The amendments to the claims should not be construed to be an acquiescence to the restriction requirement. The amendments to the claims are being made solely to expedite the prosecution of the above-identified application. The Applicant reserves the right to further prosecute the same or similar claims in subsequent patent applications claiming the benefit of priority to the instant application. 35 USC § 120.

**Response to Rejections under 35 U.S.C. § 112¶1**

Claims 1 and 8-12 stand rejected under 35 U.S.C. § 112, paragraph 1, based on the Examiner's contention that the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Specifically, the Examiner contends that although the specification is enabling for clotting components selected from fibrin, thrombin, fibrinogen, factor VIII, and factor IX, the specification is not enabling for all clotting components. The Applicants respectfully traverse this rejection.

Claims 1 and 8-12 as amended are directed to cardiovascular imaging agents, methods and kits thereof, comprising a targeting moiety wherein the targeting moiety is fibrin, thrombin, factor VIII, or factor IX. Therefore, the Applicants submit that the claims as amended are enabled by the specification as the Examiner has indicated. Accordingly, the Applicants request the withdrawal of the 35 U.S.C. § 112, paragraph 1, rejection of claims 1 and 8-12.

**Response to Rejections under 35 U.S.C. § 112¶2**

Claims 1 and 8-12 stand rejected under 35 U.S.C. § 112, paragraph 2, based on the Examiner's contention that they are indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner contends that the claims are ambiguous because it is unclear what

components of clotting Applicants are claiming. The Applicants respectfully traverse this rejection.

The claims as amended are drawn to cardiovascular imaging agents wherein the targeting moiety is fibrin, thrombin, factor VIII, or factor IX. The Applicants submit that the claims as amended are clear and definite. Accordingly, the Applicants request the withdrawal of the 35 U.S.C. § 112, paragraph 2, rejection of claims 1 and 8-12.

**Response to Rejections under 35 U.S.C. § 103(a)**

Claims 1 and 8-12 stand rejected under 35 U.S.C. § 103(a) based on the Examiner's contention that they are obvious over Goldenberg (U.S. Patent No. 5,364,612) in view of Calenoff (U.S. Patent No. 6,025,477). The Applicants respectfully traverse this rejection.

The Applicants submit that Goldenberg in view of Calenoff does not render claims 1 and 8-12 obvious because Goldenberg in view of Calenoff does not teach a cardiovascular imaging agent wherein the targeting moiety is fibrin, thrombin, fibrinogen, factor VIII, or factor IX. To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981 (CCPA 1974).

Goldenberg discloses a cardiovascular imaging agent which binds to one type of leukocyte for targeting and early imaging of cardiovascular lesion, such as atherosclerosis, vascular clots including thrombi and emboli, and myocardial infarcts and other organ infarcts, wherein the imaging agent comprises an antibody, antibody fragment, or antibody subfragment. *See* col. 3, ll. 61-67. Goldenberg further discloses that the improvement in the disclosed imaging agent lies in the use of multispecific antibody composites. The multispecific targeting antibody composite comprises at least two different substantially monospecific antibodies or antibody fragments, wherein at least one of the antibodies or antibody fragments specifically binds to one type of leukocyte and at least one of the antibodies or antibody fragments specifically binds to an antigen associated with fibrin, myosin or platelets. *See* col. 5, ll. 38-50.

It is clear from these passages and others (e.g. *see* col. 8) that the targeting moiety is an antibody. An antigen of fibrin is the target, but fibrin itself is not the targeting moiety. Contrast this disclosure with the present invention of a cardiovascular imaging agent wherein the targeting moiety is fibrin, thrombin, fibrinogen, factor VIII, or factor IX. The fact that the present claims do not claim a cardiovascular imaging agent wherein the targeting moiety is an antibody was previously discussed and agreed to by the Examiner (please see Examiner's Interview Summary dated February 9, 2005).

The Applicants submit that Goldenberg discloses a cardiovascular imaging agent comprising an antibody as a targeting moiety and not fibrin, thrombin, fibrinogen, factor VIII, or factor IX as the targeting moiety. The Applicants also submit that Calenoff does not cure this deficiency.

Calenoff discloses a reagent for use in imaging atherosclerotic plaque which comprises an antibody which binds specifically to atherosclerotic plaque antigen labeled with a detectable marker. *See* col. 14, ll. 62-65. Also disclosed by Calenoff is a method for imaging atherosclerotic plaque and adjacent normal tissue which, in part, comprises contacting the normal lumen to be imaged with an antibody which specifically binds to normal intima and/or media and which is labeled with a detectable marker. *See* col. 15, ll. 29-33. It is apparent from these passages that the imaging agents disclosed in Calenoff also comprise an antibody as the targeting moiety and not fibrin, thrombin, fibrinogen, factor VIII, or factor IX as presently claimed.

The Applicants submit that Goldenberg and/or Calenoff either alone or in combination do not teach every limitation of the present claims. Specifically, Goldenberg and Calenoff do not teach cardiovascular imaging agents comprising fibrin, thrombin, fibrinogen, factor VIII, or factor IX as the targeting moiety. Accordingly, the Applicants request the withdrawal of the 35 U.S.C. § 103(a) rejection of claims 1 and 8-12 based on Goldenberg in view of Calenoff.

#### Fees

The Applicants believe they have provided for the required fees in connection with the filing of this paper. Nevertheless, the Director is hereby authorized to charge any

additional required fee to our Deposit Account, **06-1448**.

**Conclusion**

If, for any reason, a telephonic conference with the Applicants would be helpful in expediting prosecution of the instant application, the Examiner is invited to call Applicants' Agent at the telephone number provided below.

Respectfully submitted,  
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